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VIA ECF

The Honorable Edward M. Chen
Northern District Court of California
Courtroom 5, 17th Floor
450 Golden Gate Avenue
San Francisco, CA 94102

Re: Guardant Health, Inc. v. Natera, Inc., Case No. 3:21-CV-04062

Dear Judge Chen:

Natera submits this letter to address an important question raised by the Court.

During day 1 of the pretrial conference on February 26, 2024, this Court raised the question of whether published data such as from the COBRA clinical trial (“COBRA Trial”)—referred to as “post hoc” during the hearing—is relevant retroactively to advertisements accused of being false. The question of the relevance of retroactivity was not raised in Guardant’s recent motion to strike the supplement report of Natera’s expert Dr. Hochster, who opined that the recently published final results from the COBRA Trial serve as confirmation of opinions from his opening report that Guardant’s test design was susceptible to false positives, and that false positives can lead to negative undesirable health consequences.

For clarity, the COBRA Trial was a prospective, randomized study using Guardant’s Reveal test that enrolled patients with Stage II colon cancer starting in late 2019, well before the challenged advertising of either party. The study was suspended and then terminated in late summer 2023 by its sponsor, the NRG. The results presented at the ASCO GI conference in January 2024 reflect the data collected from patients who had been enrolled in the study up through its termination. Dr. Hochster had identified the COBRA trial in his opening report as one of the ongoing clinical trials that would bear on Reveal’s clinical performance.

I. COBRA is Relevant to Technical Issues at the Heart of the Case

As this Court knows, this case arises out of claims of false advertising asserted by both parties. The COBRA Trial results are directly relevant to technical questions at the heart of this case regarding the truth or falsity of the parties’ advertisements. The parties’ respective claims implicate, among others, the following issues, all of which are directly informed by the COBRA Trial:

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1. Whether one test is superior to the other?
2. Is Guardant's tumor-naïve approach susceptible to false positive results as Natera asserted in advertising that Guardant alleges is false and misleading?
3. Are the high specificity/PPV metrics in Guardant's ads, including those which claim 100% and imply no false positives, established or are they false as Natera asserts?

The COBRA Trial—the finality of its termination and results—goes to the heart of these questions. In his August 2022 opening report, Dr. Hochster provided the opinion that Guardant's Reveal is more prone to false positives because of its test design, ¶ 24, and that the COBRA Trial is ongoing, ¶ 119. After a *Daubert* challenge, this Court ruled that Dr. Hochster's opinions regarding false positives and their potential health consequences would remain in the case. Dkt. 328 at 11-12. There is no motion to revisit that decision, and none would be proper.

NRG Oncology terminated the COBRA Trial in late summer 2023, supplying a letter to participating physicians for patients involved in the study emphasizing that “[t]he higher-than-expected ‘false positive rate’ resulted in the trial not passing the interim analysis and, as such, the trial will be closed to accrual.” Dkt. 447-2 (“Hochster Supp.”) ¶ 37. The published data confirm the higher-than-expected false positive rate.¹ As Dr. Hochster stated in his supplemental report, the outcome of the COBRA Trial confirmed his preexisting opinions. *Id.* ¶ 38.

Natera is entitled to defend itself against Guardant's claims. One of Guardant's claims is that Natera engaged in false advertising by pointing out that Guardant's tumor-naïve approach is subject to false positives despite Guardant's 2021 claims of high specificity. *See, e.g.*, TX-0068 at 2 (Natera white paper referring to challenges tumor-naïve tests face in filtering non-cancer mutations leading to false positives). Natera suspected that Guardant's tumor-naïve approach was subject to false positives, and that concern has been validated. Guardant cannot accuse Natera of false advertising – and then try to prevent Natera from showing the jury that its advertised concerns about false positives were entirely justified. The truth of Natera's concerns regarding false positives and tumor-naïve tests including Reveal is a demonstrable fact. The COBRA results support the truth of Natera's challenged statement.

Natera is entitled to support its claim against Guardant. Natera suspected from the beginning that Guardant's advertised specificity for Reveal (and thus its false positive rate) was false and misleading. For example, Guardant has claimed 100% specificity, which implies no false positives. The independent COBRA Trial and its higher-than-expected false positive rate support Natera's claim. It does not matter whether Guardant knew the 100% specificity claim was false when it made the claims (although Guardant did)—what matters is whether it was true or not. COBRA demonstrates it was not.

¹ In recent hearings, counsel has stated that the COBRA problems arose because of testing patients who were on chemotherapy. Counsel is incorrect. Higher than expected false positives were reported in the observational cohort of patients who received no treatment after surgery, and thus their results could not have been impacted by chemotherapy.

II. Caselaw Supports Later Test Results to Show Falsity

Contrary to the premise of the Court’s question, Natera does not offer Dr. Hochster’s supplement on COBRA to prove Guardant’s “state of mind.” Indeed, “[i]t is settled that intent is not an element of a Lanham Act false advertising claim.” *POM Wonderful LLC v. Purely Juice, Inc.*, 362 F. App’x 577, 579-80 (9th Cir. 2009). A claim is either false or it is not. Although state of mind may be relevant to ancillary issues such as the burden of proving actual deception or lost profits, *William H. Morris Co. v. Group W, Inc.*, 66 F.3d 255, 258 (9th Cir. 1995), the COBRA results speak to the falsity of Guardant’s advertisements and the truth of Natera’s.

The facts and holding of *Southland Sod v. Stover Seed* illuminate the distinction. In *Southland Sod*, defendant published an advertisement saying its turf is proven by study to grow slower (a desirable characteristic) than other brands. 108 F.3d 1134, 1137 (9th Cir. 1997). Plaintiff, a competitor, sued for false advertising. As well as challenging the study cited by defendant in its advertisement, Plaintiff conducted additional studies after the litigation commenced that proved the falsity of defendant’s claims. *Id.* at 1140 (Plaintiff’s expert’s “analysis of the six comparison tests [some conducted for litigation] provides adequate support for such a conclusion” of falsity). Thus, the issue—just like Guardant’s—was whether the claims in the advertisement were objectively true or not.

Similarly, in *Groupe SEB*, a plaintiff rebutted a claim of superiority alleged in defendant’s advertisements by pointing to later conducted studies. *Groupe SEB USA, Inc. v. Euro-Pro Operating LLC*, 774 F.3d 192, 202-03 (3d Cir. 2014) (“all the relevant evidence before the District Court refuted Euro-Pro’s claims of superiority.”).

III. COBRA is Relevant to Other Issues in the Case

COBRA is also relevant to other issues in the case. For instance, Guardant has alleged Natera acted improperly in raising concerns about the Parikh Study and the Reveal test with certain third parties. The COBRA trial results, including its termination, show Natera was justified in its concerns, and in its actions to raise those concerns with relevant stakeholders. As to damages, Guardant has argued lost Reveal sales were due to Natera’s alleged false advertising. However, Natera, Dr. Hochster, and others had concerns about false positives in real-world clinical use of the test, which Natera contends may explain the alleged lost sales. The COBRA Trial supports Natera’s contention. Moreover, Guardant seeks damages for prospective corrective advertising to happen after the forthcoming jury trial. The post-jury trial world, however, includes COBRA and its results which confirm Natera’s advertising regarding Reveal’s specificity. Guardant cannot obtain damages for correcting true statements, and thus its corrective advertising figure should be adjusted downward in light of COBRA.

We look forward to answering any questions the Court may have about COBRA or any of the issues raised above.

Respectfully submitted,

/s/ Kevin P.B. Johnson

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